Chapter 5
Plant Variety Rights and Food Security

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Abstract This chapter explores the origins of plant variety rights protection and the evolution of the UPOV Convention. It refers to the various revisions of UPOV and its relationship with the WTO TRIPS Agreement. It explores the impact on plant variety protection of the recent development in some patent laws which allow for the patenting of plant breeding methods. Plant variety protection in developing countries is discussed, as well as the environmental and ecological impacts of plant variety laws.

Keywords Plant variety rights protection · UPOV convention · UPOV 1991 · Patenting of plant breeding methods · Environment

5.1 Introduction

At the heart of agriculture is a complex interrelationship between farmers and seed producers. Farmers seek access to seed which is suitable for their environmental circumstances and which will secure them reasonable economic returns for their endeavours. Seed producers seek the maximum returns for their investment in seed breeding through continuing sales of their seed to farmers. The utilization of local knowledge of suitable land-races was originally the basis for selection which farmers made of seed which was appropriate for the climatic conditions and soil types within which they had to work and which produced crops that appealed to consumers. Future plantings were secured by the retention of harvested seed and by purchase or exchange of seed with other local farmers. With the application of Gregor Mendel's theories to agriculture in the early 1900s the establishment of plant breeding on genetic principles became feasible (see Allard, 1960, ch.1; Harwood, 2000; Palladino, 1994). Prior to this time farmers had, of course, selected and harvested seeds from plants which had desirable traits, such as disease resistance, and

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M. Blakeney, K. H. M. Siddique (eds.), *Local Knowledge, Intellectual Property and Agricultural Innovation*, https://doi.org/10.1007/978-981-15-4611-2_5

suitability to their local conditions, without being aware of the genetic mechanisms which produced these results (see Murphy, 2007). The significance of Mendel's theories is that it made possible the establishment of a plant breeding industry, which shifted agricultural innovation from the farmer to corporations (Kloppenburg, 2004; Palladino, 2002; Silva Dias & Ryder, 2012, cf).

To secure continuing purchases from farmers, seed companies had to offer varieties which produced yields which were superior to those superior to those which had traditionally been cultivated and which through legal protection or technological manipulation obliged farmers to purchase further supplies of seed. The development of new varieties required the identification of useful germplasm, often which had been identified and conserved *in situ* by traditional farmers, assembling diverse genetic material, crossing the genetic material to generate variation, selecting recombinations from the variation, and stabilising the preferred characteristics as a new variety. The object of varietal development was to embody selected traits, such as resistance to disease or climate stresses or high yields which would appeal to farmers. Seed breeding typically involves a three-stage process that sequentially produces 'foundation seed', 'certified seed' and 'commercial seed', usually dependent upon the regulatory system which applies in the relevant country (Gregg et al., 1980; Jaffee and Strivastava, 1994). The seed breeder has to ensure that the seed meets the claims which are made for the variety and through preservation measures, such as drying, cleaning, and chemical treatment, the viability of the seed is maintained between production and eventual utilisation. Finally, the marketing and distribution of the seed requires promotion to farmers of the characteristics and agronomic performance of available varieties through advertising and field demonstrations and distribution to farmers to ensure that the seed of the variety reaches the farmer at the correct time.

The development of the seed industry has evolved from being largely based upon traditional farmers as the primary source for varietal improvement, followed by a middle stage dominated by public sector breeding with the current structure in which private sector companies are pre-eminent. The expense of varietal development is often cited for the withdrawal of public sector from the seed industry (Knudson, 1990; Jaffee and Strivastava, 1992). This expense is also reflected in the progressive market concentration in the seed industry and its focus upon focus on high-value commercial crops and hybrids. Although the commercial seed industry accounts for approximately one third of the global market by value, in developing countries commercial seed providers are relatively insignificant, for example in India only 7% of wheat seed and 13% of rice seed in India is sourced from the formal seed sector (comprising both public and private sector bodies) (Cromwell, Friis-Hansen, & Turner, 1992; Morris, 1998 and ten Kate and Laird (1999) estimate that in many parts of Africa and Asia over 80% of total farmers' seed requirement are met from outside the formal sector.

Paralleling the developing of a seed breeding industry has been the growth primarily of industrialised countries of large scale, mechanised agriculture in which seed saving and cleaning by farmers was apparently less convenient than the purchase of farm-ready seed from dealers (see Fowler, 1994). The involvement of large

corporations in the plant breeding industry has inevitably resulted in a high degree of market concentration. Over the past three decades, a series of mergers and acquisitions created the "Big Six": Monsanto, Bayer, BASF, Syngenta, Dow and DuPont. After the introduction of herbicide tolerance genes, it made sense for firms to combine activities in pesticides, seed breeding and GM technology. The recent merger wave reduces the number of major firms to four (Bayer-Monsanto, DowDuPont/Corteva, ChemChina-Syngenta, BASF). Market concentration in the seed market has been estimated to exceed 60%, although the OECD (2018) has identified concentration levels at 100% in some markets (eg Bayer and Monsanto in the Mexican cotton market). It is uncertain whether these high concentration levels have reduced innovation in those concentrated markets (OECD, 2018) but the business model of these companies requires the sale of herbicide-tolerant seed to stimulate herbicide sales, which in turn would stimulate sales of herbicide-tolerant seed. Intellectual property protection is required to protect the investments in seed R & D.

An important question, particularly for developing countries, which are considered below, is whether the legislative protection of plant varieties has resulted in an increase in the number of varieties which are available to farmers. Even in industrialised countries, the evidence is equivocal. Lesser (1990) claims that "the availability of PBRs has increased the number of private sector breeders, as well as the number of varieties released and planted" (Lesser, 1990, 1991) whereas Butler and Marion (1985) Kloppenburg (2004) and Rangnekar (2001) consider the R&D impact of plant variety rights protection is modest at best. An intermediate position is that there is an uneven impact of plant variety protection depending upon the crop type (Perrin, Kunnings, & Ihnen, 1983; Ramaswami, 2000; Rangnekar, 2000). It has been pointed out that even in the USA, there is little evidence that plant variety rights protection has resulted in an increase in the range of plant materials available to farmers or to an increased rate of innovation (Alston & Venner, 2002; Carew & Devados, 2003; Kolady & Lesser, 2009). There is limited experience from developing countries on the impact of plant variety protection. Even if it can be shown that the protection of plant varieties has resulted in an increase in new varieties, it has been questioned whether this results in agronomically superior products or represents merely cosmetic changes in varieties or the institution of planned obsolescence (Rangnekar, 2002).

The range of crops focussed on by the large plant breeding companies do not cater for the wider needs of the farming populations in developing countries. These farmers are not a market with significant purchasing power and a substantial segment of the developing country market is supplied by non-commercial transactions, such as exchange of seed. This raises the question as to whether the absence of effective demand forestalls the supply of suitable plant varieties, or does the lack of suitable varieties pre-empt the demand for proprietary seed.

5.2 First Moves to Provide Intellectual Property Protection for Plants

The establishment of a plant breeding industry was potentially undermined by the ease with which new varieties could be replicated by competitors, since plants could easily be produced from the seeds or tubers of desirable varieties. The original breeders of these varieties sought protection for the investments which they had made in originating the varieties (Kevles, 2011). Intellectual property was called in aid to protect these investments.

The first legislative proposal for the protection of agricultural innovations was the Papal States Edict of 3 September 1833 concerning the declarations of ownership of new inventions and discoveries in the fields of the technological arts and agriculture, but this general measure was never implemented (Heitz, 1991). The first national proposal that foreshadowed the protection of agricultural innovations under patent law was the introduction, in the United States Congress of 1906, of a "Bill to amend the laws of patents in the interest of the originators of horticultural products." This bill was unsuccessful, as were similar bills introduced in 1907, 1908 and 1910. It was not until the Townsend-Parnell Act of 1930, the "Plant Patent Act," that agricultural innovations were recognised by Congress. This statute endures as sections 161–164 of the current United States patent law (35 U.S.C. §§ 161–164, 2000).

Section 161 of the Plant Patent Act confined protection to asexually reproduced plants, because of the view that sexually reproduced varieties lacked stability (see Williams, 1983). The section also excluded tuber-propagated plants principally because of a concern that this would lead to monopolies in basic foodstuffs, such as potatoes (Sanderson, 2017).

Applicants for plant patents were accordingly required to asexually reproduce the plant in relation to which protection was sought, in order to demonstrate the stability of the characteristics that were claimed.

Section 161 also required that eligible new varieties should be "distinct." The statute did not define this requirement, although the Senate Committee Report accompanying the Act stated that "in order for a new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties" and that it was not necessary for the new variety to constitute "a variety of a new species" (quoted in Rossman, 1935).

Legislation similar to the U.S. Plant Patents Act was adopted in Cuba, 1937; South Africa, 1952 and the Republic of Korea, 1973, in an endeavour by those countries to align their patent systems with that of the United States (Heitz, 1991, 23).

In other parts of the world patent protection was not considered apposite for the protection of new plant varieties. A new variety was generally characterised as a discovery, rather than as an invention (MacLeod, 1996) and the role of plant breeders in selecting desirable traits was considered to be obvious and not involving the "inventive step" of patent law (Pottage & Sherman, 2007).

5.3 The Road to UPOV

The first international instrument for *sui generis*, or specially created protection for plant varieties was the International Convention for the Protection of New Varieties of Plants (UPOV Convention) which was signed in Paris in 1961.

In Europe, the first steps toward UPOV were a French decree of 5 December 1922 which introduced a Register for Newly-bred Plants and a similar system of seed certification was established by the Netherlands in 1932. The first national statute that clearly anticipated the UPOV Convention was the Czech Law of 1921 on the Originality of Types, Seeds and Seedlings and the Testing of Horticultural Types. It provided that registration of plant seed types entitled the registrant to place its material in commerce under a registered indication. The horticulturalist or producer who produced the original material obtained the exclusive right to make use of a registered trade mark covering the type.

The U.S. Plant Patents Act 1930 was emulated in the draft Seeds and Seedlings Law, which was submitted to the German Parliament in 1930 (*GRUR* 244 [1930]), the year in which the US Act was adopted. The German legislation provided protection to plant breeders for new varieties that were distinguishable from existing varieties in characteristics that were inheritable or transferable by vegetative propagation. The German Law denied protection to a variety obtained by a mere selection without important or substantial improvement of an existing protected variety. The Law also authorised the registration of protected varieties as trademarks. However, this draft Law was never adopted by the German Parliament.

A more obvious precursor to the UPOV Convention was the German Law of 27 June 1953, on the Protection of Varieties and the Seeds of Cultivated Plants. Article 1 of this statute stated that the purpose of protection was to promote the creation of useful (*wetvoll*) new varieties of cultivated plants. An exception was provided for non-food plants and varieties intended for export. A precondition for protection was that a variety should be "individualised" and stable. This anticipated the UPOV requirements of distinctiveness and stability. The registered owner of a protected variety had the exclusive right to produce and sell seed of the variety. The Law also permitted the use of a protected variety for the creation of new varieties. Also anticipating UPOV was the requirement that anyone who marketed seed of the protected variety was obliged to use the registered designation for the variety. As with UPOV, where under the German Law the variety designation was a registered trade mark, the trade mark proprietor could not object to the use of the designation where such use was compulsory.

As with other categories of intellectual property, a key role in the inclusion of agricultural innovations within the international regulatory regime was played by industry associations. The Congrès pomologique de France, held in 1911, had called for special protection of plant varieties. The International Union of the Horticultural Profession, also considered the matter at its Congresses in Luxemburg (1911), London (1912) and Ghent (1913). The International Institute of Agriculture in its 1927 Congress had stated that the protection of a denomination was insufficient and

that a way had to be found to require "any grower who engaged in reproduction of those breeds for the purposes of sale to pay a royalty to the producer"(quoted in UPOV, 1987, 80).

The International Federation of Breeders of Staple Crops had, in its 1931 conference, expressed the hope that the legal status of new varieties should be assimilated to that of industrial inventions. Discussions concerning the creation of a new organization to agitate for the promulgation of an international legal regime for the protection of plant varieties occurred at the meetings of the International Breeders' Congress at Leeuwarden in 1936 and the 1937 Conference of the International Organization of Agricultural Industries, also held in the Netherlands. The direct result of these discussions was the foundation in Amsterdam, on November 17, 1938, of the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL). The first ASSINSEL Congress, held in Paris on 8–9 July 1939 adopted a three-point resolution:

To accept internationally the filing of trademarks and appellations as a means of protection (pending introduction of a patent);
To adopt the principle of a licence, to be drawn up by ASSINSEL for the purposes of multiplication and sale; and.
To accept internationally the definition of the word 'original' [as] seed produced, offered or sold by the breeder of the variety or under his control by his licensees or successors in title.

The Second World War interrupted these developments. At its Semmering Congress in June, 1956, a resolution of ASSINSEL called for an international conference to promulgate an international system for the protection of plant varieties. The French Government had been approached by ASSINSEL, because it had indicated a favourable attitude. Invitations were issued to 12 Western European countries[1] to attend a diplomatic conference in Paris, from 7 to 11 May 1957. The notes of invitation to the conference referred to the conclusions that had been reached at the 1954 conference on the Development of Seed Production and Trade, held in Stockholm, that there should be an international agreement favourable to the protection of new plant varieties.

5.4 The Paris Conferences on Special Protection of 1957 and 1961

The 1957 diplomatic conference in Paris was to consider establishing an international regime for the protection of plant varieties. Participation was limited by the French to those states who were known to share its own concerns on this subject.

[1] *I.e.* Austria, Belgium, Denmark, Finland, Federal Republic of Germany, Italy, the Netherlands, Norway, Spain, Sweden, Switzerland and the UK.

Thus, the United States was not invited because it had "confined itself to plant patents for vegetatively reproduced varieties, with at best only a minor part to play as foods" (UPOV, 1987, 82).

The conclusions of the 1957 Conference were set out in its Final Act, adopted on 11 May 1957. This instrument recognised the legitimacy of breeders' rights and established, as the preconditions for protection, that a variety had to be distinct from pre-existing varieties and sufficiently homogenous and stable in its essential characteristics. It defined the rights of the breeder and acknowledged the principle of the independence of protection in each country. It proposed that these principles be enshrined in an international Convention and that a Drafting Committee and a Committee of Experts be established.

Following three meetings of the Drafting Committee and two meetings of Committees of Experts, the second session of the Conference was held in Paris from 21 November to 2 December, 1961. An International Convention for the Protection of New Varieties of Plants (UPOV) was presented for the Consideration of the Conference. An important question debated there was whether the UPOV Convention would be compatible with the Paris Convention on the Protection of Industrial Property. The debate on that subject produced the inclusion of Article 2(1), which stated that "each Member of the [UPOV] Union may recognise the right of the breeder…by the grant of a special title of protection or a patent. Nevertheless, a Member State of the Union, whose national law admits of protection under both these forms may only provide one of them for one and the same genus or species."

Article 4(1) applied the draft UPOV Convention to "all botanical genera and species," but it was envisaged that the Convention would have a gradual introduction. A list of 13 genera was annexed to the Convention: wheat, barley, oats or rice, maize, potato, peas, beans, Lucerne, red clover, ryegrass, lettuce, apples, roses or carnations. Article 4(3) required each member State on entry into force of the Convention to apply it to at least five genera from this list and, within 8 years, to all the listed genera.

The UPOV Convention was signed on 2 December 1961 by the representatives of Belgium, France, the Federal Republic of Germany, Italy and the Netherlands. On 26 November 1962, the signatures of Denmark and the United Kingdom were added, followed by Switzerland on 30 November 1962. The Convention entered into force on 10 August 1968, following its ratification by Netherlands, the Federal Republic of Germany and the United Kingdom. Denmark deposited its instrument of ratification on 6 September 1968 and France on 3 September 1971. Sweden deposited an instrument of accession on 17 November 1971. Thus UPOV was from its inception, seen to be a proxy for the European seed breeding industry and its subsequent evolution involved stuttering attempts to broaden the membership of the convention.

The first step, by the revision of 1972 was to modify UPOV's budget by creating classes of membership envisaging lower subscriptions to be paid by developing countries and LDCs.

5.5 Revision of 1978

In an endeavour to broaden the membership of the Convention, invitations were widely circulated, to permit non-member states to participate as observers. In the end, some 27 non-member states attended, including the U.S. and a number of developing countries. One result was an amendment of Article 2 of the Convention to permit the accession of countries like the United States, which had laws allowing the double protection of varieties under patent and *sui generis* laws (UPOV, 1978; Byrne, 1991, 13).

The list of genera, annexed to the 1961 Convention was removed. This list had contained mainly species from temperate climates. Under the new Article 4, member states agreed to apply the Convention to at least five genera or species, rising to 24 genera or species within 8 years. Additionally, a grace period was introduced to permit the marketing of varieties 12 months prior to an application for plant variety protection being made. The revised Convention attracted the ratification of the United States on 12 November 1980, although by 1 January 1990 there were still only 18 members all of which were developed countries, mainly from Europe.

5.6 Revision of 1991

A further broadening of the UPOV Convention occurred with the 1991 Revision. The 1991 Act requires states to protect at least 15 plant genera or species upon becoming members of the Act, and to extend protection to all plant varieties within 10 years. In response to demands from breeders in industrialized counties, the 1991 Act required signatory states to make dual protection mandatory. The 1978 text merely permitted states to grant dual protection if they so desired. Through the definition of a "breeder" in Art. 1(c) as including a "person who bred, or discovered and developed, a variety," the 1991 Act makes explicit the requirement that even discovered varieties should be protected.

The 1991 Act recognized the right of breeders to use protected varieties to create new varieties. However, this exception is itself restricted to such new varieties as are not "essentially derived" from protected varieties. The drafters added this restriction to prevent second generation breeders from making merely cosmetic changes to existing varieties in order to claim protection for a new variety. The concept of essential derivation has proved highly controversial in practice, however. Breeders have been unable to agree on a definition of the minimum genetic distance required for second generation varieties to be treated as not essentially derived from an earlier variety and thus outside of the first breeder's control.

From the perspective of farmers, probably the most contentious aspect of the 1991 Act was Art. 15(2) which limited the farmers' privilege to the saving of seed for propagating the product of the harvest they obtained by planting a protected variety "on their own holdings," "within reasonable limits and subject to the

safeguarding of the legitimate interests of the breeder." Unlike the 1978 Act, the 1991 version of the farmers' privilege did not authorize farmers to sell or exchange seeds with other farmers. This was criticized as inconsistent with the practices of farmers in many developing nations, where seeds are exchanged for purposes of crop and variety rotation.

It has been suggested that for both social equity and food security reasons there are justifications for providing a farmers privilege for smallholder and resource poor farmers, especially in developing countries, whereby poorer farmers who do not represent an immediate or lucrative market would enjoy the 'farmer privilege' to save seed, while their richer counterparts would be required to pay royalties on saved proprietary seed (Spillane, 1999, 41–42).

A number of developing countries have resisted adopting the 1991 Act as the standard for plant variety protection laws. The foreign ministers of Organization for African Unity issued a statement at a January 1999 meeting calling for a moratorium on IPR protection for plant varieties until an Africa-wide system had been developed that granted greater recognition to the cultivation practices of indigenous communities (Helfer, 2001). This option is not open to those 90 or more countries that have entered into free trade agreements with the United States, since it insists that signatories adopt the 1991 version of UPOV (Drahos, 2002).

The seed saving privilege and the permitted development of non-essentially derived new varieties from protected material were compromises built in to the legislation to take account of public policy concerns. It was appreciated that permitting individuals to privatize food varieties might compromise food security if breeding material was locked up and if farmers were prevented from saving seed for further harvests. However, from the perspective of plant breeders any derivation of new varieties from their protected varieties, whether essential or nonessential, was inconvenient for them and any seed saving by farmers deprived them of new sales. Consequently, they looked to patents law, which does not contain these exceptions, to protect their new varieties.

Plant varieties can be protected in the US under a system of plant patents, or under a system of utility patents or under the Plant Variety Protection Act (PVPA). The Plant Patent Act makes available patent protection to new varieties of asexually reproduced plants. Under this scheme a plant variety must be novel and distinct and the invention, discovery or reproduction of the plant variety must not be obvious. One of the disadvantages of the scheme is that only one claim, covering the plant variety, is permitted in each application. The Federal Circuit Court of Appeals resolved any potential conflict between patent protection and protection under the Plant Variety Protection Act (PVPA) in its decision in *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc*. (200 F.3d 1374 (Fed. Cir. 2000), *cert. granted,* 148 L. Ed. 2d 954 (2001). Pioneer's patents covered the manufacture, use, sale, and offer for sale of the company's inbred and hybrid corn seed products as well as certificates of protection under the Plant Variety Protection Act for the same seed-produced varieties of corn. The defendants argued that the enactment of the Plant Variety Protection Act had removed seed-produced plants from the realm of patentable subject matter the Patents Act. The Federal Circuit rejected this argument

noting that the Supreme Court held that "when two statutes are capable of co-existence, it is the duty of the courts. .. to regard each as effective".

This was illustrated by *Monsanto Co. v. McFarling* (302F.3d 1291 (Fed. Cir. 2002)) which concerned Monsanto's patent for glyphosate-tolerant plants, the genetically modified seeds for such plants, the specific modified genes, and the method of producing the genetically modified plants. Monsanto required that sellers of the patented seeds obtained from purchasers a "Technology Agreement," in which they agreed that the seeds were to be used "for planting a commercial crop only in a single season" that the purchaser would not "save any crop produced from this seed for replanting, or supply saved seeds to anyone for replanting." Mr. McFarling, a farmer in Mississippi, purchased Roundup Ready soybean seed in 1997 and again in 1998; he signed the Technology Agreement. He saved 1500 bushels of the patented soybeans from his harvest during one season, and instead of selling these soybeans as crop he planted them as seed in the next season. He repeated this activity in the following growing season. This saved seed retained the genetic modifications of the Roundup Ready seed. Mr. McFarling did not dispute that he violated the terms of the Technology Agreement but claimed that the contractual prohibition against using the patented seed to produce new seed for planting, when he produced only enough new seed for his own use the following season, violated the seed saving provision of the PVPA. The Court declined to limit the patent law by reference to the PVPA and Mr. McFarling was found to have infringed Monsanto's patent.

5.7 The TRIPS Agreement 1994

Probably the most notorious requirement of the TRIPS Agreement is that in Article 27.3(b), which requires that Members of the World Trade Organization "shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof." The principal technical issues concerning the implementation of effective *sui generis* protection of plant varieties under Article 27.3(b) are: (a) what are "plant varieties"? and (b) what *sui generis* options are open to Member states? Article 27.3(b) requires the protection of "plant varieties," but it does not provide a definition of this term. Therefore, national laws have ample room to determine what is to be deemed a plant "variety" for the purposes of protection.

There have been lengthy discussions about the concept of "plant variety," particularly within the framework of UPOV. The scientific notion does not necessarily coincide with the legal concept. The law may require certain characteristics for a *protected* variety that may not be essential for a scientific definition. When breeders seek protection under the traditional plant breeders' rights (PBR) system, plant varieties must meet the criteria that require them to be distinct, uniform and stable (DUS). It has been suggested that "uniformity" and "stability" could be replaced by a criterion of "identifiability," which would allow the inclusion of plant populations

that are more heterogenous, and thus take into account the interests of local communities (Seiler, 1998).

The TRIPS Agreement does not prescribe any particular form of protection for plant variety innovations. It could have prescribed the UPOV Convention as the legislative norm, as it did with the Berne Convention for copyrights and the Paris Convention for industrial property. Thus, Members have the option of enacting UPOV-like protection, of including plant varieties within their patent laws, of combining both forms of protection, or of combining UPOV-like protection with biodiversity conservation legislation. The TRIPS Agreement does not prohibit the development of additional protection systems. Nor does it prohibit the protection of additional subject matter to safeguard local knowledge systems or informal innovations, as well as to prevent their illegal appropriation.

A number of developing countries had noted the tension between the development and technology transfer objectives of the TRIPS Agreement and the way in which the Agreement made it possible for rights owners to impose unreasonable terms for technologies. India, noting the difficulties faced by developing countries to obtain access to foreign technology urged that "the TRIPS Agreement may be reviewed to consider ways and means to operationalize the objective and principles in respect of transfer and dissemination of technology to developing countries, particularly the least developed amongst them".[2]

This argument was reflected in part in clause 19 of the Doha Ministerial Declaration of November 2001, which instructed the Council for TRIPS, "in pursuing its work programme including under the review of Article 27.3(b), … [to] be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension." The Doha Ministerial had set the deadline of December 2002 within which the review, referred to in Clause 19 of the Doha Declaration had referred, was to be finalised and reported to the Trade Negotiations Committee (TNC) "for appropriate action". However, after Doha, the discussions in the TRIPS Council were dominated by the consideration of the public health and patenting issue and the question of plant variety protection under Article 27.3(b) was somewhat neglected. However, in anticipation of the Cancun Ministerial, Morocco, on behalf of the African Group of countries made a Joint Communication to the Council for TRIPS, on 20th June 2003, in an endeavour to finalise the longstanding issues relating to the review of Article 27.3(b) (i) indicating the solutions that the African Group considered needed to be found; (ii) setting out possible areas of agreement on issues that have arisen; (iii) providing suggestions on how to resolve issues on which members had not been able to reach a common understanding.[3]

The Joint Communication maintained that the requirement to protect plant varieties should be consistent with and supportive of the public policy goals of Member States relating to food security, nutrition, the elimination of rural poverty, and the

[2] WTO Doc., WT/GC/W/171.

[3] WTO Doc., IP/C/W/404, 20 June 2003.

integrity of local communities. Also asserted was the importance of the preservation of the system of seed saving and exchange as well as selling among farmers in which the legitimate rights of commercial plant breeders should be protected and but balanced against the needs of farmers and local communities, particularly in developing Members.

The Joint Communication urged that in implementing the TRIPS Agreement, the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources in a mutually supportive and consistent manner, Members should retain the right to require, within their domestic laws, the disclosure of sources of any biological material that constitutes some input in the inventions claimed, and proof of benefit sharing.

5.8 Patenting of Plant Breeding Methods

A potentially important impact on plant variety protection is a recent development in some patent laws which allow for the patenting of plant breeding methods. For example, in the US a patent has been obtained for the "selective increase of the anticarcinogenic glucosinolates in brassica species" (US Patent 6,340,784, January 22, 2002) and an application published concerning a "method for breeding tomatoes having reduced water content" (US Patent Application 20100095393, April 15, 2010). This raised the possibility that methods of crop breeding to withstanding climate stress can be privatized in the US, which permits so-called methods patents.

The exclusion by the European patent legislation of "essentially biological processes for the production of plants or animals" defined in Article 2.2 of the Biotechnology Directive as consisting "entirely of natural phenomena such as crossing or selection", would have been thought to deny patent protection to plant breeding methods, but this was tested by the European Patent Office (EPO) Enlarged Board of Appeal (EBA) in two determinations, which concerned the two patents which had been granted in the USA for a process involving crossing and selection of broccoli and a process relating to the crossing and selection of tomatoes.

Both of the patent applications were opposed by interested parties. These oppositions were heard by the EPO's Technical Board of Appeal which referred a number of questions to be determined by the EBA.

The EBA ruled that a non-microbiological process for the production of plants which consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) of the European Patent Convention (EPC). The EPC takes account of the 1961 version of UPOV which specifically excludes the patenting of "plant or animal varieties or essentially biological processes for the production of plants or animals'. Rule 23b(5) of the EPC explains that a process for the production of plants and animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection". This language is replicated in the EU Biotechnology Directive which in Article 4.1

excludes from patentability: (a) plant and animal varieties; and (b) essentially biological processes for the production of plants or animals. Article 2.2 states that a process for the production of plants or animals is essentially biological "if it consists entirely of natural phenomena such as crossing or selection."

Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.

If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.

In the context of examining whether such a process is excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.

The EBA identified from the jurisprudence the following elements which had been enumerated as relevant to determining whether a process is not essentially biological:

1. The totality of human intervention and its impact on the result achieved is to be determined.
2. This has to be judged on the basis of the essence of the invention.
3. The impact must be decisive.
4. The contribution must go beyond a trivial level.
5. The totality and the sequence of the specified operations must neither occur in nature nor correspond to the classical breeders' processes.
6. The required fundamental alteration of the character of a known process for the production of plants may lie either in the features of the process, i.e. in its constituent parts, or in the special sequence of the process steps, if a multistep process is claimed.[4]

In December 2015, the European Parliament, concerned that the EBA determination might conflict with the EU plant variety legislation adopted a Resolution which asked the European Commission to look into the patentability of products derived from essentially biological processes.[5] Responding to this, on 8 November 2016, the European Commission issued a notice relating to certain articles in the EU Directive

[4] OJ EPO 2016, A27 (G 2/12) and A28 (G 2/13).

[5] P8_TA-PROV(2015)0473: European Parliament Resolution of 17 December 2015 on patents and plant breeders' rights, 2015/2981(RSP).

on biotechnological inventions in which it said that the objective of the legislators in enacting the Biotechnology Directive was to exclude not only biological processes, but also plants or animals obtained from biological processes (EC, 2016). Responding to this Notice, the EPO on 29 June 2017 took a decision to amend the its Regulations in order to exclude from patentability plants and animals exclusively obtained by an essentially biological breeding process (EPO, 2017). Following this amendment in September 2018, the EPO revoked a patent[6] granted in 2013 to Monsanto covering a type of broccoli adapted to make harvesting easier. The revocation follows an opposition filed in 2014 by a coalition of organisations, supported by 75.000 signatures (Kluwer, 2018).

5.9 Plant Variety Protection in Developing Countries

From a food security perspective, it should be noted that the UPOV Convention was originally designed to serve the interests of principally European seed breeders and in this respect reflects the industrial interests of European agriculture. Although the TRIPS Agreement does not oblige countries to follow the UPOV model in implementing their plant variety protection obligation in Art.27.3(b) of the TRIPS Agreement, developing countries have tended to adopt legislation on the 1991 UPOV model. As is mentioned above, this model circumscribes the seed-saving possibilities for farmers.

The value of PVRs for encouraging agricultural innovation in developing countries has not been authoritatively established. A UPOV study in 2005 looked at the impact of PVP laws in Argentina, China, Kenya, Poland and the Republic of Korea (UPOV, 2005). It concluded that the impact of PVP varies country-by-country and crop-by-crop. In Argentina, the introduction of new, protected varieties from non-resident breeders was observed in important agricultural crops (e.g. soybean, lucerne) and in horticultural crops (e.g. rose, strawberry). The demand for new, protected varieties was shown by their increased proportion of the certified seed area by 80–90%, particularly, in soybean and wheat. An increase of horizontal cooperation in the seed industry, involving foreign seed companies and agreements for technology transfer between national research institutes and breeding entities with other national companies resulted in more rapid movement of germplasm.

As China's PVP systems have only been in operation for less than 10 years and for a limited number of genera and species and it was not yet possible to evaluate their full impact. Nevertheless, a rapid uptake by farmers of new, protected varieties seen, for example, in maize and wheat in Henan Province was noted, with an increase in the number of breeders in that province, as well as the introduction of new, protected varieties for major staple crops (e.g. rice, maize, wheat),

[6] European patent number 1.597.965.

horticultural crops (e.g. rose, Chinese cabbage, pear), including traditional flowers (e.g. peony, magnolia, camellia) and for forest trees (e.g. poplar).

In Kenya, an increase in the number of varieties developed and released in the 6-year period after the introduction of PVP (1997–2003), compared to the previous 6-year period (1990–1996), across a number of agricultural crops and for maize in particular was noted. Also, the study noted the diversification of the horticultural sector (for example the emergence of the flower industry) and the increased introduction of foreign germplasm in the form of new, protected varieties (especially of horticultural crops).

In the Republic of Korea, a particular impact was the extension of protection to a range of agricultural and horticultural crops, including traditional crops (e.g. ginseng) and varieties of ornamental crops such as rose. The report also noted the stimulation of rice breeding.

A joint project of the Anti-American Institute for Cooperation in Agriculture and the University of Amsterdam carried out in 1994, examined 'the (expected) impact of plant breeders' rights (PBR) on developing countries with respect to: private investment in plant breeding, breeding policies of public institutes, transfer of foreign germplasm, and diffusion of seed among farmers' (Jaffé & van Wijk, 1995). Five countries were used as case studies of which three (Argentina, Chile and Uruguay) had PVP systems already in place, and two (Colombia and Mexico) were about to introduce them. These countries are similar in the sense that there are basically two seed markets. The hybrid seed market is controlled by transnational corporations, whereas the seed market for self-pollinating varieties is dominated by domestic firms. However, Argentina differs from the others in that it is the only country in which PVP right owners have successfully enforced their rights to the extent that their control over seed supply for wheat and soya is comparable to that of their counterparts in the United States. This led the authors of the study report to conclude that in all probability, PVP in that country has 'prevented the local wheat companies from reducing or even terminating their breeding activities and triggered the reactivation of some soya bean breeding programmes'.

In a 2002 study for the UK Commission on Intellectual Property Rights (CIPR), Rajnekar observed that the release of new varieties as an indicator of the impact of PVPs was equivocal evidence as a number of inquiries remain before a conclusive statement on the impact of PBRs on varietal release rates can be accepted as an economic good (CIPR, 2002). First, there is only partial evidence on rates of varietal release in the pre- and post-PVR period. Secondly, the availability of varieties is not necessarily an economic good in itself, as it might be that the increase in varieties may be part of wider appropriation strategies involving planned obsolescence as a means of maintaining market shares, which result in faster rates of varietal turnover and higher varietal release rates. The Final Report of the CIPR noted that the evidence relating to the impact of plant variety protection on research was sparse and mainly from developed countries and indicated that there was little or no evidence that total R&D activity had increased as a result of the introduction of PVP, suggesting that that the main impact of PVP was as a marketing tool (CIPR, 2002).

A UNEP study of 1996 stated that there was "mixed and inconclusive evidence" about the direct benefits of introducing IPRs in plant varieties in developing countries (UNEP, 1996).

Rangnekar concluded that existing evidence of the focus of private sector plant breeding was not entirely promising because "the range of crops focussed on and the type of agro-ecological niches being targeted do not cater to the wider needs of the majority farming populations in developing countries" (Rangnekar, 2002).

No country has yet introduced food security concerns as a factor in implementing plant variety rights protection. However, Kenya, one of the first developing countries to have PVP legislation when it passed the Seeds and Plant Varieties Act, 1975 contains a requirement that 'the agro-ecological value [of the variety] must surpass, in one or more characteristics, that of existing varieties according to results obtained in official tests.' It should be noted however, that there was little demand from domestic breeders for this legislation; it being precipitated more by foreign horticultural firms.

5.10 Environmental Impacts of Plant Variety Protection Laws

The environmental and ecological impacts of plant variety laws is also significant from a food security perspective. The high yielding hybrid varieties developed by seed breeding companies has been particularly attractive to farmers. For example, *Zea mays* a maize hybrid had yields 25% greater than standard maize. This was a technological guarantee of future seed sales, as hybrid vigour tended not to be transmitted between generations (see Kingsbury, 2009). However, this had unfortunate side-effects as traditional varieties were replaced by the hybrid causing a loss of genetic diversity. *Zea mays* was susceptible to affliction by the fungus *Helminthosporium maydis* (southern corn leaf blight). By 1970, 80% of the US crop was vulnerable to *H. maydis* and in the wet summer of that year around 20% of the US crop was lost to the blight (Allaby, 2019). A similar loss of genetic diversity has been experienced with the other major cereals (Sofia, 2012; Ahuja & Mohan, 2016).

Another environmental impact of hybridisation is that while it increases the yield in first generation crops, the quality and quantity of subsequent crops deteriorates, and continues to deteriorate, with each replanting. As a consequence, hybridisation operates as a de facto technological protection system obliging farmers to purchase new seed for subsequent plantings (Hubicki & Sherman, 2005). However, hybridisation has only successfully been used in a limited number of crops; it is not used in barley, cotton, millet, rice, soybeans and wheat (Goeschl & Swanson, 2003).

A more effective alternative to hybridization is the genetic manipulation of seed to prevent the germination of any saved seed (see Blakeney, 2004/2005). On 3 March, 1998, the United States Department of Agriculture and the Delta & Pine Land Company were registered as assignees of a US patent "to control plant gene

expression".[7] This technology that allowed plant breeders to modify crops so that after germination, they would produce sterile seed. This technology was first known as the "Technology Protection System", after which it has become known as "Genetic Use Restriction Technology" (GURT). There are two types of GURTs: (i) v-GURTs: where the use of a crop variety is controlled through genetically induced seed sterility; and (ii) t-GURTs: where the use of a trait, such as disease resistance or early ripening is controlled. GURTs use "a chemical sensitive genetic switch (responsive, for example, to alcohol or the antibiotic tetracycline) linked to a gene for an enzyme which activates a toxin gene. In the t-GURT system when the toxin gene is switched on, it becomes active in the late stage of seed formation to prevent it germinating (see Daniell, 2002). An advantage of GURTs is that, unlike hybridization, they are applicable to all seeds. As a technological fix it avoids some of the embarrassing publicity from law suits by seed companies against farmers to enforce their intellectual property rights in relation to proprietary seeds, as well as the cost, inconvenience and unpredictability of intellectual property litigation (CFS, 2005; Leahy, 2005).

Pat Mooney, member of the organisation formerly known as Rural Advancement Foundation International (RAFI), now known as the Action Group on Erosion, Technology and Concentration (ETC Group) has coined the term 'Traitor technology' to describe GURTs as a whole and 'Terminator Technology' to describe v-GURTs (Oczek, 2000). This opprobrium is generated, in part, by concerns that if the sterility trait spreads beyond the confines of a field where the GURTs are planted it could produce a 'suicide-plant pandemic' that wipes out an entire species (Mander, 2002). In any event, it is suggested that v-GURT plants could cross-pollinate with non-genetically modified plants, either in the wild or on the fields of farmers who do not adopt the technology. This cross-pollination could reduce yield in the subsequent year due to occurrence of sterile seeds in neighbouring stands This outcrossing is of particular concern where ecological niches and wild relatives exist locally, particularly in the centres of origin of a crop (UNEP/CBD, 2003). An ad hoc technical group meeting of UNEP/CBD also suggested that the application of GURTs might produce low quantities of autotoxic compounds in seeds or other tissues, which may negatively impact non-target organisms (e.g. birds, insects and soil biota).[8] It was also speculated that GURTs might negatively impact the food chain and affect human health due to the additional traits, such as the transfer of allergenicity genes and the transfer of antibiotic resistance (UNEP/CBD, 2003). On the other side of the coin, the National Research Council in the USA has commended v-GURTs as an effective method of confining gene flow (NRC, 2000).

From an intellectual property perspective, it has been suggested that the protection which v-GURT technology assures the seed breeder may go well beyond the time limits of patent and plant variety rights protection (Kariyawasam, 2009), but on the other hand, after the expiry of those rights, the technology is available for reverse

[7] See U.S. Pat. No. 5723765.

[8] *Ibid.*

engineering (Lai, 2014). This is, of course, more likely to be a matter for seed companies than farmers.

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